

Appl. No. 09/284,009  
Amdt. dated December 8, 2004  
Amendment under 37 CFR 1.116 Expedited Procedure  
Examining Group

PATENT

**REMARKS/ARGUMENTS**

Claim 87 has been revised to expressly point out the inherent functional feature of the regulatable element. Non-limiting examples of sites where the regulatory element functions include a hypoxic site, an ischemic site, a stress site, and a site that is a combination of at least two of an hypoxic site, and ischemic site, and a stress site. Support for claim 87 as revised is provided in the instant application at least at page 6, lines 18-20; page 8, lines 4-13; page 9, lines 11-22; and page 11, lines 15-18.

A comparison of revised claim 87 and claim 88, which is dependent from claim 87, shows that both define the claimed mononuclear phagocyte in part based on the functionality of the regulatable element at sites having conditions of hypoxia, ischemia, and/or stress. Accordingly, Applicants believe that the content of claim 88 is fully within the scope of claim 87. To avoid the possible interpretation of both claims as identically encompassing a phagocyte active at such sites, claim 88 has been canceled without prejudice for re-presentation in a continuing application. Similarly, claim 110, which was dependent from claim 88, has also been canceled without prejudice for re-presentation in a continuing application.

Claim 89 has been revised to be consistent with the cancellation of claim 88 and to remove extraneous language from the claim without altering claim scope. Support for the removal of the language is found in claim 89 as previously presented.

Claim 91 has been revised to use the term "element" for consistency with claim 87, from which claim 91 indirectly depends. Support for the term is found at least in claim 87.

A comparison of revised claim 89 and claim 109, both of which are dependent from claim 87, shows that both claims are directed to a mononuclear phagocyte with a binding agent. To avoid the possible interpretation of both claims as identical, claim 109 has been canceled without prejudice for re-presentation in a continuing application.

Claim 111 has been revised to reflect the inherent capability of the binding agent recited in the claim. Support for the revision is provided at least on page 7, lines 2-5, of the application as filed.

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Claim 116 has been revised to refer to *ex vivo* embodiments of the claimed methods without prejudice for pursuit, in a continuing application, of the difference in subject matter between the claim as revised and as previously presented. Support for the revised claim is provided at least at page 17, lines 10-17; and page 37, line 12, to page 38, line 5, of the instant application.

Claims 120 and 121 have been revised to remove the term "pharmaceutical" from the preamble of the claims without altering the intended scope thereof, especially in light of the retention of language in the body of the claim. Support is provided by the claims as previously presented.

Claim 122 has been revised to remove extraneous language based on helpful comments by Examiner D. Nguyen as discussed below. Applicants believe that the scope of the claim has not been narrowed because expression, whether induced or naturally occurring, under regulation by an HRE must occur under "suitable hypoxic" conditions. Support for the revised claim is provided at least by the inherent characteristics of an HRE, which is responsive to hypoxic conditions.

No new matter has been introduced, and entry of the above claims is respectfully requested.

#### Telephonic interviews

Applicants wish to express their thanks for the courtesy of an interview on 22 November 2004 between Examiners Celine X. Qian and David Nguyen as well as Ms. Jill Martin of Biomedica, USA (representative of the assignee at interest). The undersigned joined the interview by telephone. The Examiners offered helpful suggestions on possible revisions to the claims to address the rejections of record and to advance the application towards allowance. Applicants' representatives offered input on alternate revisions and indicated that they would consider the Examiner comments and consider possible revised claims for presentation.

On 26 November 2004, the undersigned submitted draft claims, not for entry but for consideration by the Examiners and further discussion. On 2 December 2004, Examiner

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Qian telephonically contacted the undersigned with additional suggestions for revisions to the claims. Applicants made further revisions to the claims and provided them to the Examiners for consideration, but not entry, on 3 December 2004. On 8 December 2004, Examiner Qian called the undersigned and indicated that the revised claims would be acceptable for allowance, having overcome all issues in the application.

The above listing of claims contains all of the revisions provided on 3 December 2004 and indicated as allowable on 8 December 2004.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 87-93, 101, 104, 109-116 and 120-125 were rejected under 35 U.S.C. § 112, first paragraph as allegedly enabled by the application as filed only with respect to delivery and expression of "a reporter or marker gene." Applicants again traverse this rejection based on the previously presented reasons and arguments.

However, and in light of the telephonic discussions with the Examiners as described above, Applicants believe that this rejection was either withdrawn during the first interview as not applicable, or as having been obviated by the above revisions to the claims. In either case, this rejection is believed to no longer be applicable to the above claims.

Withdrawal of the instant rejection is thus respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 89-93 were rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite with respect to the location of the "binding agent" as recited in the claims. Applicants again respectfully traverse based on the previously presented reasons and arguments.

However, and in light of the described above telephonic discussions with the Examiners, Applicants believe that this rejection was either withdrawn during the first interview as not applicable, or as having been obviated by the above revisions to the claims. In either case, this rejection is believed to no longer be applicable to the above claims.

Withdrawal of the instant rejection is thus respectfully requested.

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Claim 110 was rejected as allegedly indefinite.


As presented above, claim 110 has been canceled without prejudice for re-presentation in a continuing application. Accordingly, Applicants respectfully submit that this rejection may be properly withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858-350-6151.

Respectfully submitted,

  
Kawai Lau, Ph.D.  
Reg. No. 44,461

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, Eighth Floor  
San Francisco, California 94111-3834  
Tel: 858-350-6100  
Fax: 415-576-0300

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